

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and these comments.

Claim 2 is cancelled presently, and claims 8 - 11 and 13 - 17 have been withdrawn from consideration. Claims 1 and 6 are amended, as supported in the specification, *e.g.*, at paragraph [0069]. Claim 6 is revised to correct grammatical errors. Thus, no new matter is added.

Upon entry of this response, claims 1, 5 – 11, 13 – 17, and 19 – 21 will be pending.

### **I. Claim Objections**

The examiner objects to claim 6 as informal. By virtue of the above-mentioned revision to claim 6, the ground for objection are moot, and so withdrawal is requested.

### **II. Claim Rejections under 35 U.S.C. 103**

Claims 1, 2, 5-7 and 19 stand rejected under over Bett *et al.*, U.S. Publication No. 2004/0106194. With the understanding that Bett disrupts the E1 gene region in order “to obliterate E1 gene functions,” the examiner contends that the deletions prescribed in the present claims “do not appear to provide an advantage over [the] similar deletions” of Bett.

This impression of “no advantage” may relate back to a misapprehension over the state of the relevant art, particularly as evidenced by Havenga *et al.* That is, the examiner states that the “art teaches (Havenga *et al.*) that the pIX gene is found from nucleotides 3400 to 4660.” Office Action at page 6, lines 3 – 6. Yet, Havenga actually teaches that “[i]n the case of B2-group adenovirus ... one of four putative [pIX] promoters coincided with the sole pIX cap site within Ad35 virus... ranging from [nucleotides] **3234 to 3488**” (page 2138, left column, at lines 17 – 21; emphasis added).

To advance prosecution, therefore, applicants have revised the claims to prescribe a nucleotide deletion between nucleotides **367 and 2917** (claim 1). This contrasts with Bett, which teaches deletion of the entire E1 region (nucleotide 457 and 3402), including the pIX

promoter between nucleotides 3234 and 3488. The presently claimed vector retains the pIX promoter elements in the E1B region, in other words, while vectors in the cited art do not.

Havenga evidences that recombinant adenovirus vectors of prior art, as illustrated by the Bett vector, are unstable due to, “low pIX expression induced by removal of the pIX promoter located in the E1B region of B-group viruses” (page 1 in the abstract, lines 4-6). Accordingly, retention of the pIX promoter in applicants’ claimed vector yields an improvement, unheralded by the contemporaneous literature, in Ad35 genomic stability and transfection efficiency. See specification at paragraphs [0054] – [0055].

Thus, the presently claimed invention differs structurally from and is functionally advantageous over the vector of Bett. Since the examiner’s contrary impression is incorrect, applicants request entry of the present amendments and withdrawal of this rejection.

Claims 1, 2, 5 – 7. and 19 – 21 also are rejected over Bett in view Wadell *et al.*, U.S. 2004/0136958. Applicants would emphasize, however, that Wadell not only fails to cure the deficiencies of Bett, discussed above, but also omits any suggestion of “transfection” of CD34+ cells by adenovirus (Ad35), as presently recited. While Wadell teaches that Ad35 virions bind CD34+ cells with a high affinity, there is no mention of infection of CD34+ cells by Ad35 virions, much less Ad35-mediated expression of a transgene (*e.g.*, “transfection”) within CD34+ cells. Even in instances when virions bind to CD34+ cell surfaces, that is, the cells are not necessarily infected, much less transfected. Accordingly, applicants request that withdrawal of this rejection, too.

## CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Marvich also is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is

authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

Date 30 December 2008

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